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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,259	11/14/2003	Elaine Merisko-Liversidge	029318-0979	8061

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 10/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/712,259	MERISKO-LIVERSIDGE, ELAINE	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-15 and 17-39* is/are pending in the application.

4a) Of the above claim(s) *19-23* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-15,17,18 and 24-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of response and amendment dated 7-27-06 is acknowledged.

Claims 1, 3-15 and 17-39 are pending. Claims 2, 16 and 40-93 have been canceled. Claims 19-23 have been withdrawn. Accordingly, claims 1, 3-15, 17, 18 and 24-39 have been examined.

The following is a new rejection:

Claim Rejections - 35 USC § 112

Claim s 24-28 recite the limitation "particle size of less 2 microns and less than 1900 nm". There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

Claims 1, 3-15 and 24-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,145,683 to Rhodes.

Rhodes teaches nifedipine containing pharmaceutical composition wherein nifedipine is in the form of finely divided microcrystalline particles having a particle size of less than 100 microns (abstract). In particular, Rhodes teaches tablet formulation (example 1), which meets the instant limitation of claim 2. The composition yields a slow release of nifedipine (col. 1). With respect to the claimed surface stabilizer, Rhodes

teaches polyvinyl pyrrolidone. Rhodes teaches particles less than 100 microns, which includes less than 1000 nm as claimed. Further, Rhodes teaches the same active agent for treating the same condition i.e., hypertension. Therefore, in the absence of any unexpected result with respect to the particle size, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to choose an appropriate particle size of the microcrystalline nifedipine because Rhodes suggests that a quick release formulation releasing nifedipine with a bioequivalence of 100 ng/ml or greater and a slow release formulation with a bioequivalence of 20-80 ng/ml is attained with a particle size less than 100 microns. With respect to the claimed plasma profiles, the claims limitations presented recite an intended use and carries no patentable weight. Further, the composition of Rhodes contains all the essential elements of the instant claims and hence the composition exhibits the claimed pharmacological profiles.

Claims 1, 3-15 and 24-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,562,069 by itself or '069 in view of US 5,145,683 Rhodes.

'069 teaches nifedipine compositions for treating cardiovascular and coronary disorders, wherein the nifedipine has a particle size of about 1 to 10 microns and a suitable surface stabilizer such as PVP. '069 fail to teach particles less than 1000 nm. However, in the absence of any unexpected with respect to the particle size, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to choose an appropriate particle size of the microcrystalline nifedipine in the composition

of '069 because the difference between the claimed upper limit of particle size and the lower limit taught by '069 is 1 nm. Alternatively, Rhodes suggests that a quick release formulation releasing nifedipine with a bioequivalence of 100 ng/ml or greater and a slow release formulation with a bioequivalence of 20-80 ng/ml is attained with a particle size less than 100 microns. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to optimize the particle size of nifedipine crystals so as to achieve a slow and a fast release or a controlled release. With respect to the claimed plasma profiles, the claim limitations presented recite an intended use and carries no patentable weight. Further, the composition of Rhodes contains all the essential elements of the instant claims and hence the composition exhibits the claimed pharmacological profiles.

Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,562,069 by itself or '069 in view of US 5,145,683 Rhodes, as applied to claims 1, 3-15 and 24-39, and further in view of US 4,814,175.

'069 and Rhodes, discussed above, fail to teach the claimed combination of nifedipine with other agents. "175 teach a combination of particulate nifedipine and a beta blocker for treating cardiovascular diseases. Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to combine nifedipine of Rhodes or '069 with other therapeutic compounds such as beta blockers because '175 suggests a combination therapy of nifedipine and beta blocker

and one of an ordinary skill in the art would have expected to treat cardiovascular diseases with a combination of nifedipine and beta blocker compounds.

Response to Arguments

Applicants' arguments with respect to pending claims are moot in view of the new rejection.

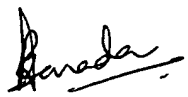
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Primary Examiner
Art Unit 1615
October 12, 2006